IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW MEXICO

HOPE HUERTA as Next Friend and Parent of BLANCA M. VALDEZ-HUERTA, a minor,

Plaintiffs,

vs. Civ. No. 09-485 RHS/LFG

BIOSCRIP PHARMACY SERVICES, INC., and DOES 1-25,

Defendants.

MEMORANDUM OPINION AND ORDER

THIS MATTER is before the Court on the Plaintiffs' *Daubert Motion to Exclude Testimony of Chris Clardy, M.D.*, filed May 24, 2010 [Doc. 183]; and on the Plaintiffs' *Daubert Motion to Exclude Lloyd Vernon Allen, M.D.'s Opinions and Testimony*, filed May 24, 2010 [Doc. 184]. The parties have not requested a hearing. Having considered the parties' submissions and the relevant law, the Court concludes that both motions should be denied.[1]

I. Legal Standards.

Under Federal Rule of Civil Procedure 702:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

[1] Pursuant to 28 U.S.C. § 636(c) and FED. R. CIV. P. 73(b), the parties have consented to have me serve as the presiding judge and enter final judgment. *See* Docs. 8, 25.

The "overarching subject [of an inquiry under Rule 702] is the scientific validity—and thus the evidentiary relevance and reliability—of the principles that underlie a proposed submission." *Daubert v. Merrill Dow Pharm.*, 509 U.S. 590, 594 (1993)

> . . . . The subject of an expert's testimony must be "scientific [, technical, or other specialized] knowledge." The adjective " scientific" implies a grounding in the methods and procedures of science. Similarly, the word "knowledge" connotes more than subjective belief or unsupported speculation. The term "applies to any body of known facts or to any body of ideas inferred from such facts or accepted as truths on good grounds." Webster's Third New International Dictionary 1252 (1986). Of course, it would be unreasonable to conclude that the subject of scientific testimony must be "known" to a certainty; arguably, there are no certainties in science. . . . Instead, it represents a process for proposing and refining theoretical explanations about the world that are subject to further testing and refinement" (emphasis in original)). But, in order to qualify as "scientific knowledge," an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by appropriate validation- *i.e.*, "good grounds," based on what is known. In short, the requirement that an expert's testimony pertain to "scientific knowledge" establishes a standard of evidentiary reliability.
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> . . . .[A]n expert is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation. *See* Rules 702 and 703. Presumably, this relaxation of the usual requirement of firsthand knowledge-a rule which represents "a 'most pervasive manifestation' of the common law insistence upon 'the most reliable sources of information,' " Advisory Committee's Notes on Fed. Rule Evid. 602, 28 U.S.C. App., p. 755 (citation omitted)-is premised on an assumption that the expert's opinion will have a reliable basis in the knowledge and experience of his discipline.
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> Faced with a proffer of expert scientific testimony, then, the trial judge must determine at the outset, pursuant to Rule 104(a), whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.

Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 589-93 (1993) (footnotes omitted). Thus, "[a]n expert, no matter how good his credentials, is not permitted to speculate." *Goebel v. Denver & Rio Grande W. R.R. Co.*, 215 F.3d 1083, 1088 (10th Cir. 2000). "[T]he factors identified in

Daubert may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 150 (1999). "The objective of [*Daubert's* gatekeeping] requirement is to ensure the reliability and relevancy of expert testimony. It is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Id.* at 152.

II. Analysis

A. Dr. Clardy's testimony.

Dr. Clardy is a pediatric nephrologist hired as an expert by BioScrip. The Plaintiffs contend that Dr. Clardy's testimony should be excluded pursuant to *Daubert* and Rule 702 because Dr. Clardy allegedly used an "improper certainty standard as the basis of his opinions," making them unreliable and inadmissible. Doc. 183 at 4. They urge the Court to exclude Dr. Clardy's opinion "to the extent it challenges the Plaintiff's treating and expert physicians . . . ." and to strike the first three conclusions of his expert-witness report. Doc. 183 at 1. These conclusions are:

> 1. It is not certain that [Blanca's] rejection in May 2006 was caused by inadequate tacrolimus. It may have been caused by the change from [Cellcept] to [Imuran] in February 2006.
> 2. It is not certain that [Blanca] had a low tacrolimus level when she was admitted to UNMH in May 2006 as a level was not measured until the second hospital day, after she had been on a reduced dosage.
> 3. If [Blanca] had a low tacrolimus level upon admission to UNMH in May 2006, then it is not certain that this low level resulted from using an inadequate preparation of tacrolimus. Other possibilities are that her vomiting impaired her absorption, that she missed some doses, or that something interfered with the drug's clearance.

Doc. 183, Ex. A at 1. Plaintiffs contend that the correct legal standard for medical opinions is "to a reasonable degree of medical probability" and that Dr. Clardy "incorrectly opines that the

opinions of Plaintiffs' experts are untrustworthy or unreliable because they are not certain or that they cannot be proven." Doc. 183 at 3. The Court disagrees with the Plaintiffs' interpretation of what Dr. Clardy "opines." A fair reading of Dr. Clardy's written report indicates that, by discussing what was "not certain," and noting at his deposition that there was no direct evidence that BioScrip had dispensed subpotent or inadequate medication, *see* Doc. 200, Ex. A at 3-4, he was demonstrating that *his* opinions were based only on "appropriate validation- *i.e.*, 'good grounds,' based on what is known." *Daubert*, 590 U.S. at 594. As he more fully explained in his deposition testimony, Dr. Clardy stated, "I think there are numerous possibilities [for the transplant rejection], and it's a matter of looking at those possibilities and saying which things are likely, which things are less likely and trying to figure out based on that, you know, what the probability is of various explanations." Doc. 200, Ex. A at 2. He then examined the probability of various explanations for Blanca's rejection based on what facts were known, *i.e.* what facts were "certain." For example, Dr. Clardy explained that patients can suffer an "acute rejection" when they are changed from Cellcept, which is a "more efficient or more powerful" immunosuppressant drug, to Imuran – a fact that is certain to have happened to Blanca. *See id.* He also noted the "certain" fact that Blanca had experienced a subsequent episode in 2007 of "undetectable drug levels" of both tacrolimus and another immunosuppressant in her system not associated with the tacrolimus suspension that BioScrip formerly provided, which was remedied to a "normal" level when Blanca's ingestion of tacrolimus and the other drug was supervised in the hospital - which indicated non-adherence to the drug prescriptions instead of subpotent tacrolimus. *See id.* at 3, 5-6. Dr. Clardy referred to medical

articles stating that there is a 30-70% prevalence rate of non-adherence to prescribed medical plans in pediatric patients. *See* Doc. 215, Ex. A at 4-5. Based on these two certain facts or "data," and the medical research showing that 30-70% of pediatric transplant patients are non-adherent in taking medications as prescribed, Dr. Clardy expressed the opinion that, though it was theoretically "possible" that Blanca's rejection could have been caused by an improper preparation of the tacrolimus suspension, there was a 75 to 80 percent "probability" that the cause of Blanca's rejection was a combination of non-adherence or some other reason for insufficient levels of tacrolimus in her system other than subpotency, plus the change from Cellcept to Imuran. *See* Doc. 200, Ex. A at 2-3. The Court concludes that Dr. Clardy's opinions are based upon correct legal standards and methodologies.

In their reply brief, the Plaintiffs raise a new basis for exclusion of Dr. Clardy's testimony: that it allegedly "does not amount to scientific knowledge." Doc. 208 at 4. The basis for this objection is statements Dr. Clardy made at his deposition explaining why he disagreed with Dr. Wong's *belief*[2] that Blanca's family had adhered to the prescription regimen in May 2007 when Blanca had no detectable levels of immunosuppressant medication in her system notwithstanding the fact that, when Blanca was administered the prescribed dosages in the hospital, her

[2] There is no contention that Dr. Wong personally administered Blanca's drugs to her on a daily basis and, therefore, he could only base his belief that Blanca's family had given her the medications as prescribed on their statements that they did – if that is what they told him. The Plaintiffs have failed to attach Dr. Wong's statements to their motion, which makes it virtually impossible for the Court to ascertain exactly what the statements or opinions were with which Dr. Clardy disagreed.

immunosuppressant levels returned to normal. First, Dr. Clardy noted that treating physicians, including himself, sometimes bond with their patients to a degree that they no longer objectively look at facts. *See id.* at 5. He then noted that, although Dr. Wong had "speculated" that the amoxicillin Blanca was taking may have interfered with the absorption of her immunosuppressant medications in 2007, Dr. Clardy could find no support for that theory in any of the medical literature regarding transplant rejections and drug interactions, and that Dr. Clardy's opinion that there was no support for that theory was also expressed by Drs. Alexander and Morganstern, two of Plaintiffs' other medical experts. *See id.*; Doc. 215, Ex. A at 9-11. Although the Plaintiffs contend that Dr. Clardy "did not offer any explanation" for disagreeing with Dr. Alexander's opinion apparently regarding non-adherence (which the Plaintiffs fail to set out, attach, or quote in their motion or reply brief), *see id.*, Dr. Clardy explained, "I know for a fact Dr. Alexander when he was deposed was not familiar with the fact that the levels had been undetectable in May 2007," *see* Doc. 215, Ex. A at 9. Dr. Clardy's opinions regarding why he disagreed with some statements made by Dr. Wong are based on the facts presented in this case, and on his medical knowledge arising from research and personal experience in his role as a nephrologist who deals with transplant patients. His opinions are, therefore, sufficiently based on scientific knowledge to be reliable, relevant, and admissible. The Court concludes that Dr. Clardy's opinions challenged in the Plaintiffs' motion are based upon scientific knowledge that will assist the trier of fact to understand or determine a fact in issue.

B. Dr. Lloyd Vernon Allen's testimony.

The Plaintiffs move to disqualify as an expert witness Dr. Allen, a pharmacist with a doctoral degree whom BioScrip has identified as an expert witness for the purpose of testifying regarding the standard of care of pharmacists and pharmacies, and whether BioScrip met the applicable standard of care in its operations and record keeping. As grounds, the Plaintiffs allege that Dr. Clardy has a professional relationship with Dr. Tom Kupiec, an expert designated by the Plaintiffs, which Plaintiffs allege creates a "gross conflict" of interest that makes Dr. Allen's opinions unreliable. *See* Doc. 184 at 1-2.

The Plaintiffs contend that Dr. Allen

> maintains constant communications with Dr. Kupiec both in person and by email. Dr. Allen has discussed this case briefly on at least one occasion and Dr. Allen and Dr. Kupiec work together on a number of projects. Dr. Allen further testified that Dr. Kupiec and his laboratory is the exclusive laboratory Dr. Allen uses for quality assurance testing on his sponsored/paid studies by pharmaceutical companies.

Id. at 3. These facts, Plaintiffs contend, make a jury "unable to verify the reliability of the opinions expressed by Dr. Allen." *Id.*

The Plaintiffs misstate Dr. Allen's testimony. Dr. Allen testified that he communicates, usually by e-mail, with Dr. Kupiec "about once every week or two," and that he worked with him on projects "maybe a couple times a year," but that he did not have "anything right now that he is doing any analytical work on." Doc. 184, Ex. 3 at 6. Dr. Allen works with two other laboratories, but testified that when the selection of a laboratory for quality assurance work is up to him, he always selects Dr. Kupiec's laboratory if Dr. Kupiec has "the analytical capability." *Id.* at 7-8. In February 2010, in the course of casual conversation, he mentioned to Dr. Kupiec that he "has a

tacrolimus case." *Id.* at 3. Dr. Kupiec responded, "Uh-oh. We had a contact about that case." *Id.* Dr. Allen testified that they "immediately stopped talking about it. We do not talk about cases that are – there may be some overlap in." *Id.* at 3-4. Dr. Allen "did not know which side [Dr. Kupiec] was on. I did not ask any questions. We immediately stopped talking about that and went on to other things." *Id.* at 5.

The Plaintiffs do not contend in their motion that they have identified Dr. Kupiec as a testifying expert. In fact, they do not allege that Dr. Kupiec or his laboratory has done anything in their case, including testing the tacrolimus suspension dispensed by BioScrip that is at issue. The only evidence in the record is that the Plaintiffs or their attorneys made "a contact" of an undisclosed nature with Kupiec's laboratory, but nothing more. *See id.* at 3. The Plaintiffs have stipulated that they will not elicit any testimony that "any laboratory testing was conducted" on the tacrolimus BioScrip dispensed to Blanca in April and May 2006 or call any expert to testify "that any laboratory testing conducted on the April and May 2006 Tacrolimus suspension liquid medication . . . dispensed by [BioScrip] . . . was subpotent." *See* Doc. 188, Ex. D at 1-2. The Plaintiffs have failed to allege facts showing any conflict of interest, much less the "gross conflict" that they contend exists. The Court and a jury can readily determine the reliability of Dr. Allen's testimony based on his scientific knowledge and experience notwithstanding the fact that he has a working relationship with another expert whom the Plaintiffs merely contacted at some point in the past.

IT IS ORDERED that the Plaintiffs' *Daubert Motion to Exclude Testimony of Chris Clardy, M.D.* [Doc. 183] and their *Daubert Motion to Exclude Lloyd Vernon Allen, M.D.'s Opinions and Testimony* [Doc. 184] are DENIED.

Robert Hayes Scott

ROBERT HAYES SCOTT
UNITED STATES MAGISTRATE JUDGE
Presiding by Consent